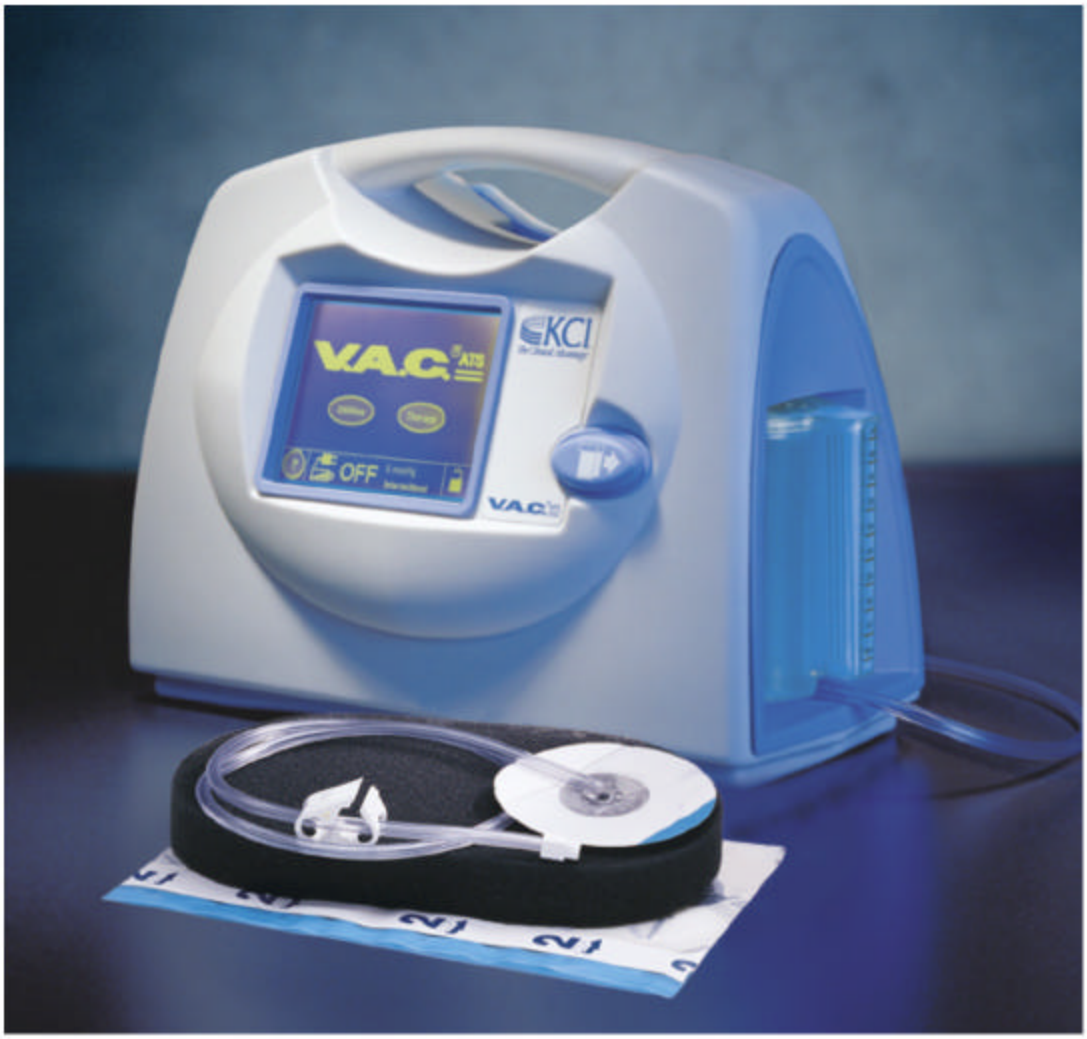
V.A.C.® ATS



Operations and Maintenance Manual

RESTRICTED USE

Certain pages of this manual are designated "Restricted Use Only." Information contained on those designated pages may be used solely to facilitate the proper maintenance and repair of KCI products identified herein. If these terms are unacceptable, immediately remove those designated pages and return them to KCI, Attn: Legal Dept. Refer to qualified service personnel who are authorized by KCI for proper maintenance and repair

KCI®

The Clinical Advantage®

P/N M6252211 REV E 18/11/02

Caution

Federal law restricts this device to sale or rental by or on the order of a physician.

In order for KCI products to provide safe, reliable and proper performance, the following conditions must be adhered too. Failure to comply with these conditions will void any applicable warranties.

- Assembly, operations, extensions, re-adjustments, modifications, or repairs are carried out by qualified personnel authorized by KCI.
- The electrical installation of the room complies with the appropriate national electrical wiring standards.
- The equipment is used in accordance with the accompanying documentation and applicable labelling.
- Technical maintenance for the product is performed by qualified personnel authorized by KCI.

Subject to confidentiality protections, satisfactory to KCI, KCI will make available upon request circuit wiring diagrams, component part lists, descriptions, calibration instructions, or other information which may assist the user's appropriately qualified personnel to repair those parts of the equipment designated by the manufacturer as repairable.

Although this equipment conforms to the intent of the directive 89/336/EEC in relation to Electromagnetic Compatibility, all electrical equipment may produce interference. If interference is suspected, move equipment from sensitive devices or contact the manufacturer.

WARRANTY INFORMATION

IN THE UNLIKELY EVENT OF A DEFECT IN MATERIALS OR WORKMANSHIP, A LOCAL KCI OFFICE, SUBSIDIARY OR AUTHORIZED AGENT WILL REPAIR, REPLACE OR SUPPLY REPLACEMENT PARTS UNDER STANDARD WARRANTY TERMS AND CONDITIONS IN EFFECT AT TIME OF PURCHASE. WARRANTY TERMS AND CONDITIONS ARE SUBJECT TO CHANGE AT ANYTIME WITHOUT NOTICE. WARRANTY TERMS AND CONDITIONS ARE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL KCI BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES AND EXPENSES, INCLUDING DAMAGES TO PROPERTY, DUE IN WHOLE OR IN PART TO THE USE OF THE PRODUCT UNLESS OTHERWISE EXPRESSLY REQUIRED BY LAW.

IN THE EVENT OF DEFECT, REPAIR WORK SHOULD BE COMPLETED BY RETURNING THE THERAPY UNIT TO A LOCAL KCI OFFICE, SUBSIDIARY OR AUTHORIZED AGENT. CONTACT KCI FOR YOUR NEAREST LOCATION.

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V.A.C.® THERAPY CLINICAL APPLICATIONS

Indications:
Indicated for patients who would benefit from a sub atmospheric pressure device particularly as the device may promote wound healing. This includes patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or intermittent sub atmospheric pressure.

Types of wounds for which V.A.C.® Therapy has been indicated include chronic, acute, traumatic, sub acute and dehisced wounds, partial - thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts.

Contraindications:
Contraindicated for patients with **malignancy** in the wound, untreated **osteomyelitis**, unexplored fistulas, non-enteric **fistulas**, or **necrotic** tissue with eschar present. Do not place V.A.C. dressing over **exposed blood vessels or organs**.

Precautions: Always Follow Universal Precautions
Precautions should be taken with patients exhibiting active **bleeding**, difficult wound **hemostasis**, or who are on **anticoagulants**.
When placing the V.A.C. dressing in proximity to **blood vessels or organs**, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers that form a complete barrier between them and the V.A.C. foam dressing. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a barrier, vessel or organ.

Wounds with enteric fistulas may require special precautions in order to optimize V.A.C. Therapy. Refer to the *V.A.C. Therapy Clinical Guidelines* for sample guidelines additional information on clinical applications and therapy considerations. For recommended protocols, please consult the treating physician.

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V.A.C.® THERAPY CARE AND SAFETY TIPS

KEEP THERAPY ON

Never leave sub atmospheric pressure off for more than 2 hours per day. Remove V.A.C.® dressing if subatmospheric pressure is terminated or is off for more than 2 hours per day.

DRESSING CHANGES

Perform aggressive wound cleaning per physician order prior to dressing application. Routine dressing changes should occur every 48 hours. Dressing changes for infected wounds should be accomplished every 12–24 hours. Always replace with sterile V.A.C. disposables from unopened packages. Follow established institution protocols regarding clean versus sterile technique.

Note: All components of The V.A.C. System are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All V.A.C. Therapy disposables (including the foam, canister, tubing and drape) are latex free.

MONITORING THE WOUND

Inspect the dressing frequently to ensure foam is collapsed and negative pressure is being delivered in a consistent manner. Monitor periwound tissue and exudate for signs of infection* or other complications. Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without V.A.C. Therapy, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock and various other complications.

IF DRESSING ADHERES TO WOUND

Instill normal saline into the dressing and let it set for 15–30 minutes, then gently remove the dressing from the wound. Consider placing a single-layer, wide-meshed, non-adherent dressing prior to foam placement.

DISCOMFORT

If patient complains of discomfort **throughout** therapy, consider changing to white PVA Versa Foam™ dressings. If patient complains of discomfort during the dressing change, consider pre-medication, use of a non-adherent prior to foam placement or instillation of a topical anesthetic agent such as 1% lidocaine without epinephrine prior to dressing removal.

UNSTABLE STRUCTURES

Over unstable body structures such as unstable chest wall or non-intact fascia, use continuous (not intermittent) therapy to minimize movement and stabilize the wound bed.

SPINAL CORD INJURY

In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system) discontinue V.A.C. Therapy to help minimize sensory stimulation.

BODY CAVITY WOUNDS

Underlying structures must be covered by natural tissues or synthetic materials that form a **complete** barrier between the underlying structures and the V.A.C. foam dressing.

V.A.C. DISPOSABLES

The V.A.C.® ATS therapy unit is to be used exclusively with V.A.C. ® disposables.

WARNING: Do not pack the foam into any areas of the wound. Forcing foam dressings in a compressed manner into any wound is contrary to KCI recommendations.

*Signs of possible infection may include fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound area, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, sore throat with swelling of the mucous membrane, disorientation, high fever (>102F, 38.8 C), refractory hypotension, orthostatic hypotension, or erythroderma (a sunburn-like rash) may be added signs of more serious complications of infection.

FEATURES

- **T.R.A.C.™ Technology**

T.R.A.C.™ (Therapeutic, Regulated Accurate Care). Technology allows accurate sensing of negative pressure applied at wound site. This feature helps ensure that the target therapy pressure is maintained, even during patient movement.

- **500ml Canister**

A large capacity canister with an integrated hydrophobic and charcoal filter provides bacteriological protection and significantly reduces odor from collected exudate.

- **On-Screen User Guide**

User help screens assist operation.

- **Easy-to-Use Touch Screen**

Allows operator to more easily view and change V.A.C.® ATS therapy settings

- **Removable Power Cord**

Detachable power cord allows greater patient mobility and flexibility.

- **Integrated Battery and Charger**

Provides up to 4 hours battery life. An automatic charging facility switches to battery power when AC/mains power is removed.

- **Extended Pump Life**

Linear, brushless pump with increased life expectancy.

- **Intensity Setting**

The speed at which the target pressure setting is achieved can be varied in accordance with varying wound conditions and pain tolerance as directed by a treating physician.

- **Adjustable Negative Pressure Settings**

Negative pressures can be set between 50 and 200mmHg in increments of 25 mmHg, as directed by a treating physician.

- **Adjustable Therapy**

Application of negative pressure can be selected for continuous or intermittent application, as directed by a treating physician.

- **Therapy Hour Meter**

The total time therapy is applied can be displayed and reset by the caregiver.

- **Integrated IV Pole Clamp**

Allows the therapy unit to be attached to a range of IV poles: 2.2 to 5cm (.9” – 2”)in diameter.

- **Therapy Lockout**

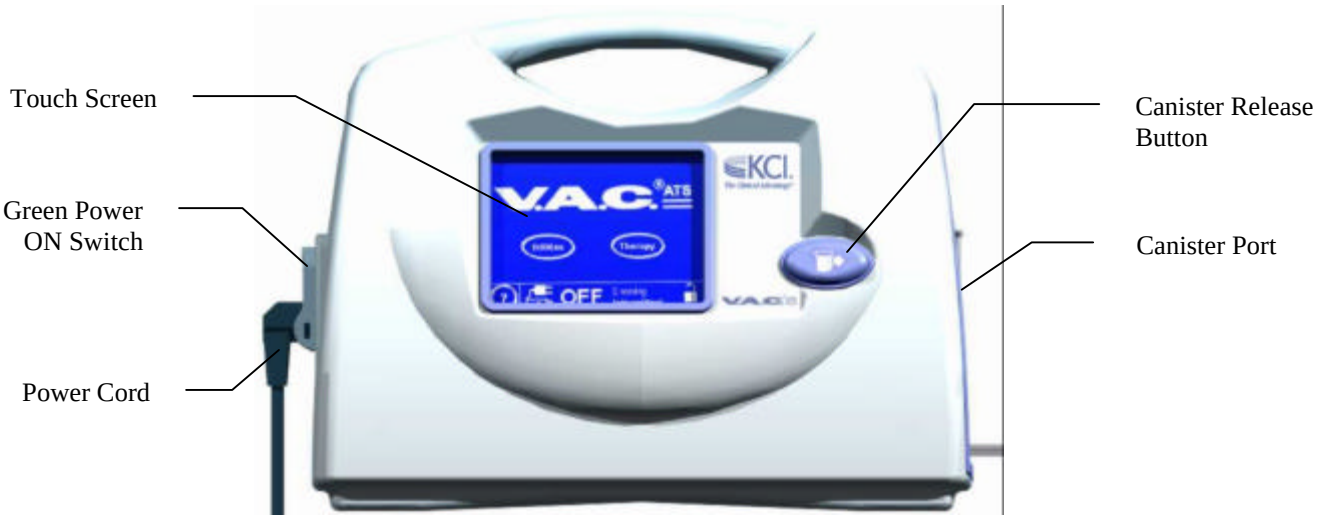
The caregiver can disable the touchscreen controls to prevent unwanted changes.

- **Footboard Hanger**

Extended hanger arm can fit over a range of footboard designs.

OPERATING INSTRUCTIONS

Setting up the V.A.C.® ATS Unit



1. **Apply dressing** according to instructions listed on page 8. For canister installation, please refer to page 9.

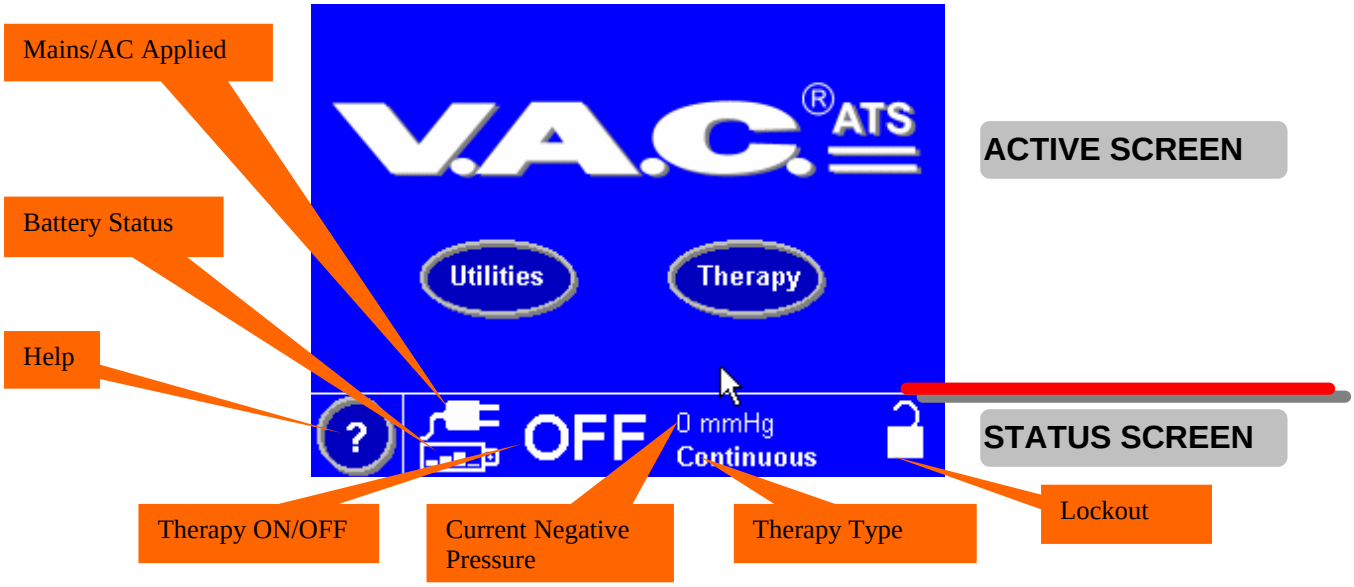
2. **Place the therapy unit** on the footboard of the bed using the self adjusting hanger which accommodates up to a 7.5cm (3”) thickness footboard. Alternatively the therapy unit can be hung on a suitable IV pole using the integrated IV Pole Clamp located on the rear of the case. Always operate therapy unit in an upright position.

CAUTION:
The IV Pole Clamp should only be used on poles that are in excess of 2.2cm (.9”) diameter and are securely attached to a bed frame or a stable stand. To ensure stability of the therapy unit on the IV pole, it should be clamped no higher than 2 times the width of the pole base. The clamp should be sufficiently tightened to ensure that the therapy unit cannot slide down the pole.

3. **Attach the power cord** to the V.A.C.® ATS unit and connect to a suitable power supply.

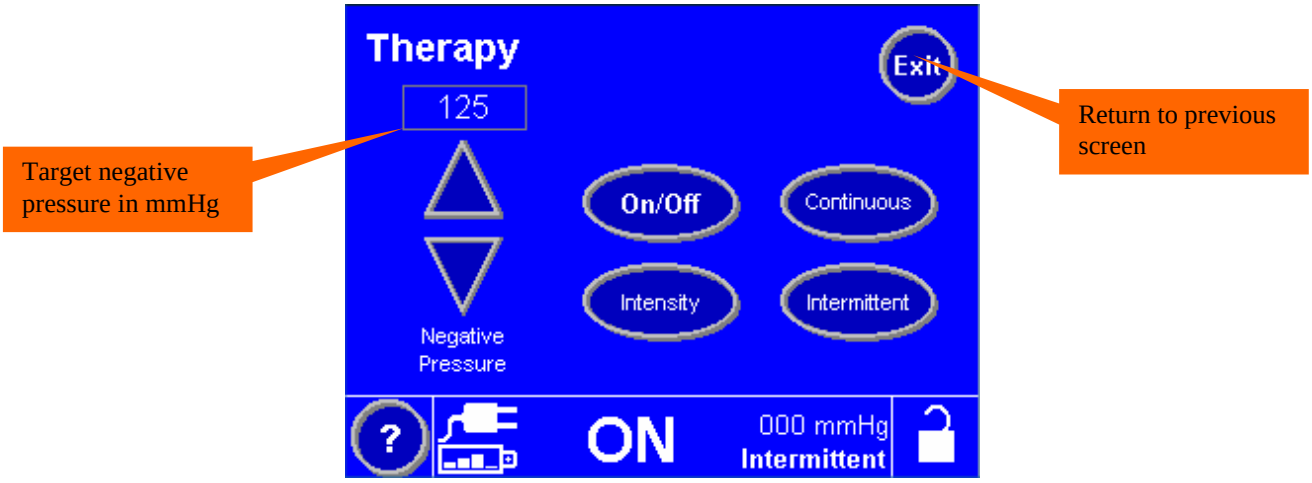
4. **Turn on power** to the therapy unit by pressing the green Power ON switch above the power cord.

OPERATING INSTRUCTIONS (contd.)



HOME SCREEN

5. **Press Therapy button** to select Therapy Screen.



THERAPY SCREEN

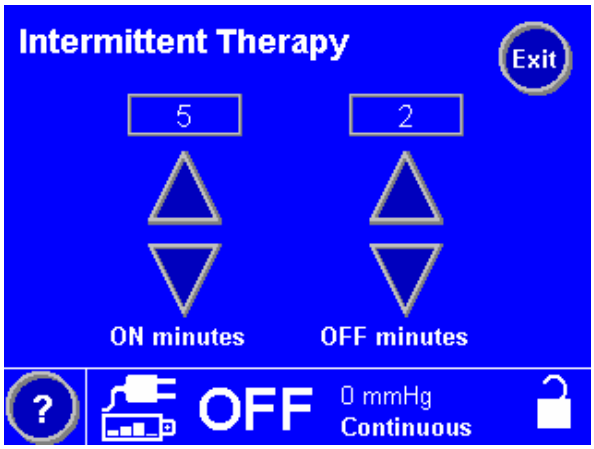
6. **Select level of negative pressure:**
   Use arrow keys to increase or decrease therapy levels between 50 and 200mmHg, as per physician order.The therapy unit is set at a standard negative pressure of 125mmHg.

OPERATING INSTRUCTIONS (contd.)

7. Select Continuous or Intermittent therapy:

The standard setting is Continuous therapy. If you select Intermittent, this will take you to the Intermittent Therapy screen.

The standard setting for intermittent therapy is 5 minutes on and 2 minutes off.

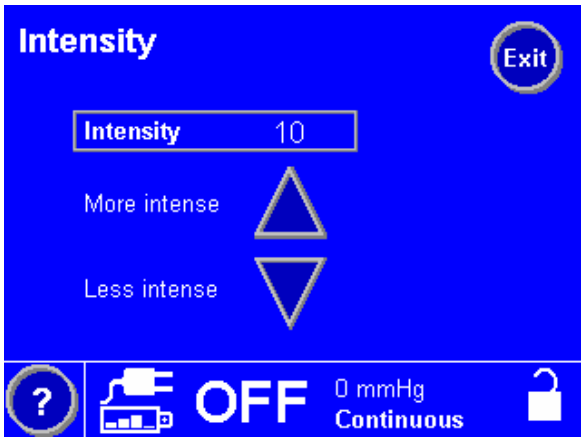


Use the arrow keys to increase or decrease On and Off times between 1 and 10 minutes in accordance with recommended physician guidelines. Press exit to confirm selection and return to Therapy screen.

8. Select Intensity level:

The intensity level is the rate of negative pressure change at the wound site in mmHg per second. The lower the intensity level, the more gradual the negative pressure increases to the desired setting. This option is especially useful for patients who may experience pain and discomfort during initial pull down and release of the foam, especially during intermittent therapy.

The Intensity option ranges from 10 to 50mmHg/sec in increments of 5. The standard setting is 10. It is recommended that new patients start therapy at the standard setting of 10 and increase gradually according to patient tolerance and needs. The intensity can also remain at the minimum setting throughout the entire length of treatment to enhance patient comfort.

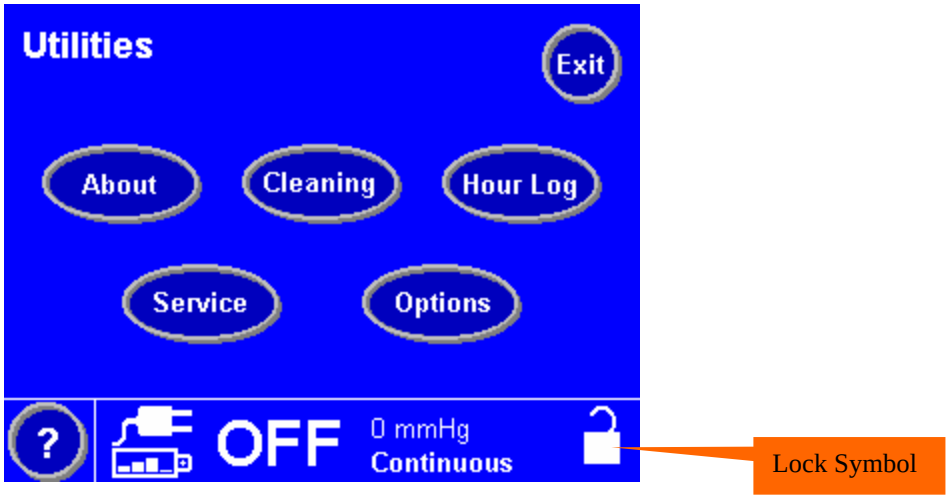


Use the arrow keys to increase or decrease pressure change at the wound site in mmHg per second. This should be adjusted in accordance with varying wound conditions, patient tolerance and at the direction of a physician.
Press Exit to return to the Therapy screen.

OPERATING INSTRUCTIONS (contd.)

Lockout Feature

This feature is most useful in preventing individuals from tampering with therapy unit controls or settings. However, it is important that other clinicians in your facility understand how to lock and unlock the screen before the feature is used. The lockout feature is available from all screen menus; example shown is the Utilities Screen.

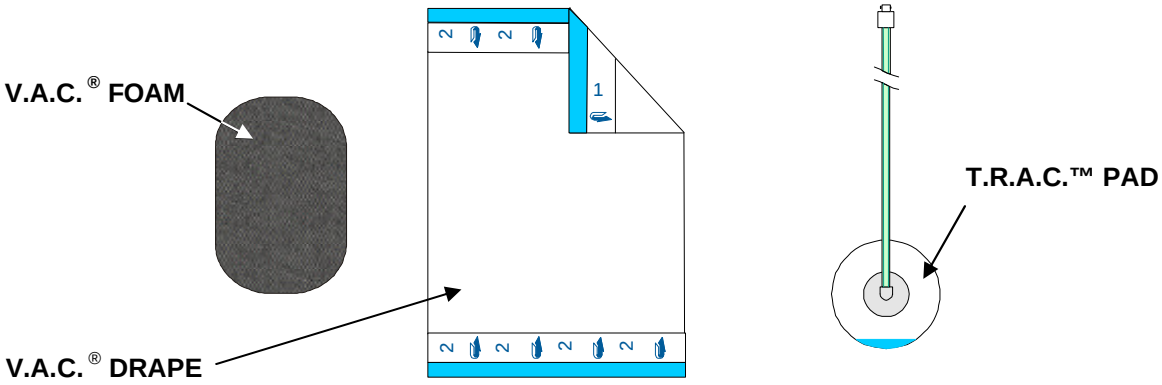


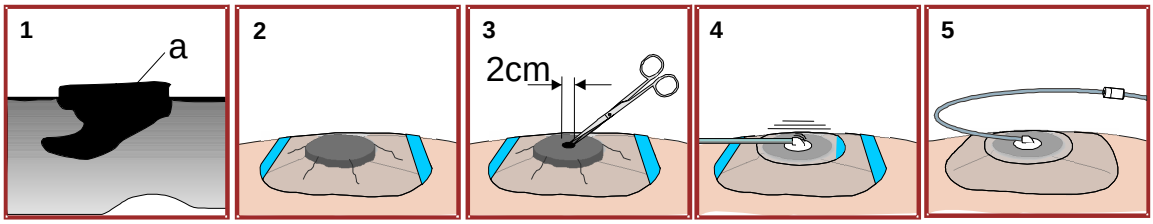
To Lock Touchscreen:
Press the Lock symbol for 3 seconds to disable the touchscreen user controls.
The lock symbol will now be closed to indicate the touchscreen controls are locked.

To Unlock Touchscreen:
To unlock the controls press the lock symbol for 3 seconds.
The lock symbol will now be open to indicate the controls are unlocked.

APPLYING THE DRESSING

Pouch Contents Identification





1. Perform aggressive wound care per physician order prior to V.A.C.® Dressing application.

2. Cut the V.A.C.® foam to fit the size and shape of the wound, then place the foam (a) into the wound cavity. Avoid cutting foam directly over wound to prevent particles from entering wound bed.
   Warning: do not pack the foam into any areas of the wound. Forcing foam dressings in a compressed manner into any wound is contrary to KCI recommendations.

3. Size the drape to cover the foam and 3-5 cm of surrounding intact skin. Trim drape if necessary. Remove the white backing liner (labeled **1**) and place drape on foam. Remove top support layer (labeled **2**) and pat around drape to ensure an occlusive seal.

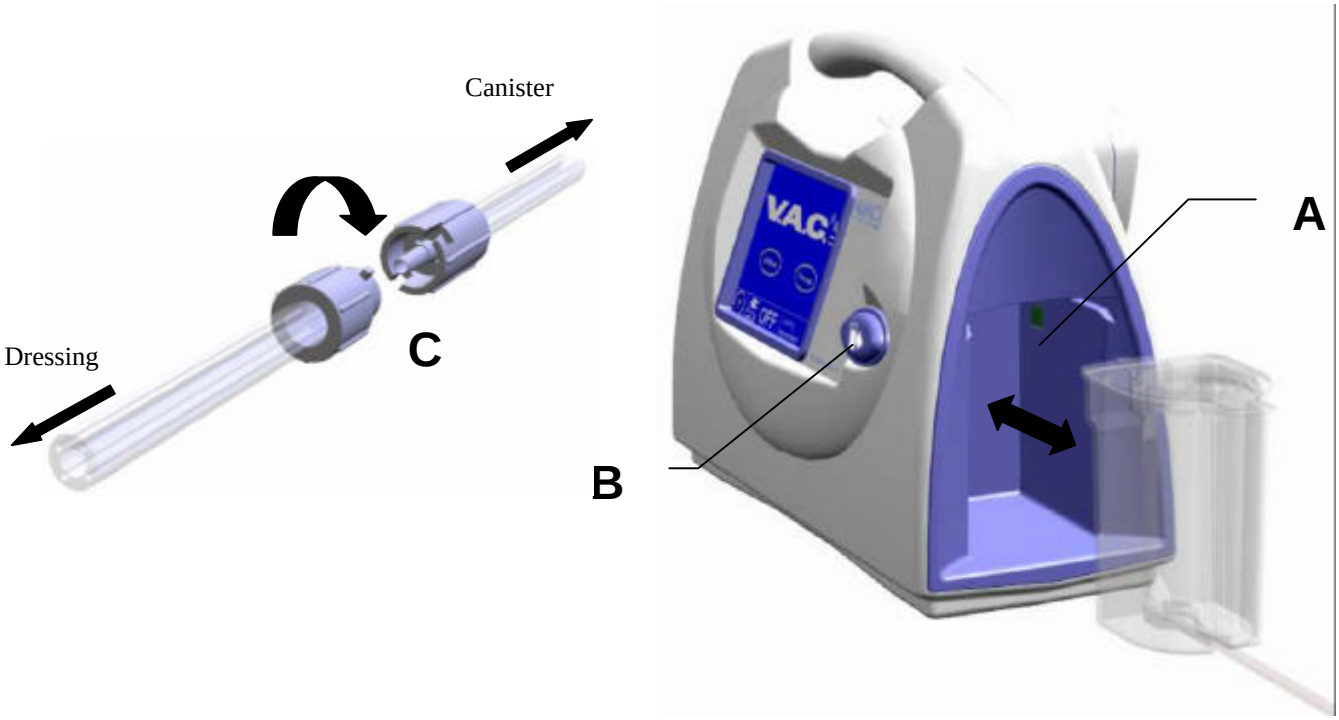
4. Choose a location on the drape where you would like to apply the tubing. At this location, cut a hole through the drape, approximately 2 cm in diameter, leaving the foam mostly intact. An alternative is to cut a 2 cm diameter hole into the drape before you lay it down on the foam. Either process of cutting the drape will work.
   Note: Always cut a 2cm hole in the drape. Do not cut a linear "slit" in the drape. When negative pressure is applied, a slit may collapse and close, preventing negative pressure from reaching the wound

5. Remove the backing liner (labeled **1**) from the T.R.A.C.™ Pad. Place the T.R.A.C. Pad on the drape, with the hole in the center of the T.R.A.C. Pad elbow directly over the hole in the drape. Gently pat around the T.R.A.C. Pad to ensure complete adhesion. Remove the support layer (labeled **2**).

6. Remove the blue handles from the drape and T.R.A.C. Pad, where applicable. Connect dressing tubing to canister tubing.

7. Refer to page 9 for canister installation.

NOTE: DO NOT Cut off the T.R.A.C. Pad and insert the T.R.A.C. tubing into the foam. This will cause the therapy unit to alarm



Canister Installation

1. Slide the canister into the canister port **(A)** until an audible click is heard ensuring that it is fully inserted.
2. Connect the two halves of the T.R.A.C.™ connector **(C)** together by twisting until it locks in place.
3. Verify that both clamps are open.
4. Turn therapy ON.

Canister Removal

1. Turn therapy off.
2. Close clamps on canister and dressing tubing.
3. Twist T.R.A.C. Connector **(C)** to disconnect canister tubing from dressing tubing.
4. Press canister release button **(B)**, then pull out the canister.
5. Dispose of canister according to hospital protocols.

Additional canisters and dressings are available and can be ordered through your local KCI representative.

DISPOSAL OF V.A.C. ATS DRESSINGS AND CANISTERS

Disposal of used V.A.C.® ATS dressings and canisters

After patient use, all disposable parts of the system should be treated as contaminated.

These include:

- All tubing and related connectors and clamps
- Canister
- V.A.C.® ATS dressing and drape.

Hand and eye protection should be used when handling any body fluids or waste. Properly dispose of all disposable parts according to institutional procedures and local, state and federal laws and regulations. Use universal precautions.

ALARMS

A visual alarm will be indicated on the screen followed by an audible alarm under the following conditions:

ALARM TYPE	NOTIFICATION	REMEDY
CANISTER FULL	Visual message accompanied by audible alarm.	Change canister and restart therapy
TUBING IS BLOCKED	Visual message with audible prompt which cancels after 1 minute if blockage is cleared. After 5 minutes of blockage therapy is turned off and full alarm is sounded.	Ensure tubing clamps are open. Check that tubing is not kinked or pinched.
TUBING AND/OR DRESSING HAS LEAKS	Visual message with audible prompt after 2 minutes which cancels if leak is sealed. After an additional 2 minutes, a full alarm is sounded and after 5 minutes therapy is turned off.	Pat around drape to check for leaks. If leak is identified patch the leak with extra drape. Ensure T.R.A.C.™ connector is properly locked. Ensure V.A.C. ® ATS canister is fully engaged.
THERAPY IS NOT ACTIVATED	Visual message accompanied by audible alarm after 15 minutes with Therapy Off.	Turn Therapy ON
BATTERY IS LOW	Audible alarm accompanied by a visual message before shut down.	Connect therapy unit to a Mains/ AC power source to recharge the battery.

Silencing the Alarm:
Press the MUTE button on the alarm screen to silence the alarm for two minutes.

After correcting the alarm condition, you can press the CONTINUE button to silence the alarm and return to the HOME screen.

CARE AND CLEANING

Protection Against Contamination

To help reduce the risk of infection and contact with contaminated blood or body fluids during the dressing change or cleaning of equipment, it is important to protect all exposed skin and mucous membranes.
Protective clothing includes:

- Disposable gloves.
- Disposable impervious gown (if splashing of blood or body fluids is possible).
- Protective eyewear to help protect from splashing of cleaning solution and/or blood or body fluids.
- Protective mask.

Always follow Recommended Safety Precautions and use universal precautions.

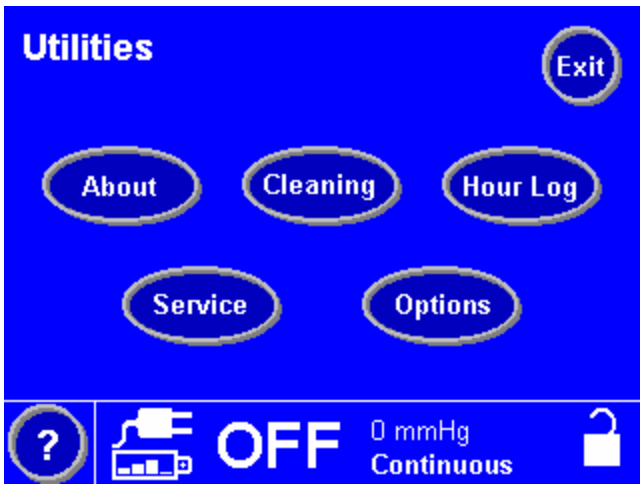
Inspect Power Cord Regularly

The power cord should be inspected regularly for damage and wear. Replace damaged or worn power cords, immediately. Power cords are available from KCI.

Cleaning Surface of the Therapy Unit

The V.A.C.® ATS unit should be wiped weekly with either a diluted solution of bleach (50ml in 5 liters) or mild disinfectant. The cloth should be damp, not dripping, to avoid getting excess fluid anywhere on the therapy unit. Other chemicals should not be used as they may damage the V.A.C. ATS unit enclosure.
NOTE: ***Patient does not typically need to be removed from the V.A.C. ATS when performing weekly cleaning procedures.***

If the therapy unit is being cleaned when therapy is being applied to a patient, it is important to disable the touchscreen to ensure that no inadvertent commands take place.



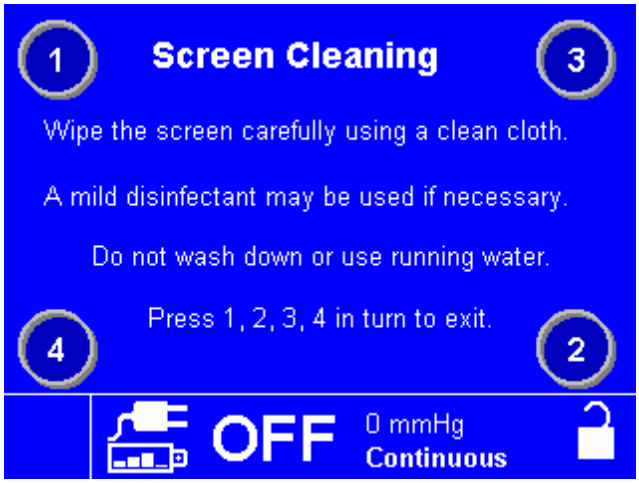
UTILITIES SCREEN

To disable the touchscreen:

1. Press the Exit button on each screen until the Home Screen is displayed.
2. Press Utilities.
3. Press the button marked Cleaning to enter the Cleaning Screen that automatically disables the main areas of the touchscreen.

CAUTION: The electrical telephone style connector inside the canister housing is for KCI service use only. Care should be taken when cleaning to ensure that no fluid enters this connector.

CARE AND CLEANING (contd.)



CLEANING SCREEN

4. Wipe the screen with a clean dry cloth. If necessary, use a slightly damp cloth and wipe dry.

5. Follow the instructions on the screen to exit back to the Home Screen.

BATTERY OPERATION

Automatic switch to battery power

The V.A.C.® ATS will automatically revert to battery operation if AC/mains power is disconnected. Therapy unit will operate at previous settings. The plug icon will no longer appear on the screen and the battery icon will appear. Once the V.A.C. ATS is plugged back into the wall, AC/mains power is restored and the battery will automatically re-charge while the therapy unit remains plugged in.

- **Average battery time** (after full recharge): approximately 4 hours, depending on the settings.
- **Average time to recharge battery**: approximately 4 hours fast charge to reach 85% capacity; approximately 10 hours to reach full charge.
- **Low battery alarm**: One tick mark within the battery indicator signals approximately 25% of battery time is left. An audible alarm will sound when the battery is very low, then the therapy unit will switch to Therapy OFF. However, the touchscreen may still remain functional at the time of a low battery alarm.
- **Automatic shutdown**: If the battery charge falls below a critical level, the therapy unit will automatically turn off and will remain off even if plugged into AC/mains power. To restore power, turn the therapy unit off then on again using the green power switch.

MAINTENANCE

Periodic Maintenance

The following procedures should be performed on a routine basis by suitably qualified personnel at the frequency specified. Records shall be kept of this maintenance.

1.0 Change the secondary hydrophobic filter after 3 months of use, or immediately if there is evidence of contamination on the canister side of the filter. When changing this filter, the date of the next filter change is written on the filter.

2.0 To ensure correct Therapy performance, perform a Pump Pressure Test every 2 years. Refer to the relevant procedure for details of this test, available from the KCI Technical Centre. If the pump fails to pass the Pressure Test, it should be replaced.

3.0 Perform a capacity test on the battery pack every 12 months.

- Leave the Therapy unit connected to the mains/AC supply for at least 8 hours to fully charge the battery.
- Disconnect the unit from the mains power and run ‘continuous’ therapy at 125mmHg with a canister that has a tubing cap fitted.
- If a ‘Battery Exhausted’ alarm sounds in less than 2 hours, the battery pack should be replaced.

The battery should be changed at 28 months intervals regardless of the above capacity test.
Refer to the ‘Battery History’ label on the underside of the Therapy Unit for the manufacturing date of the unit’s battery.

Important Note on Battery Disposal: The battery packs include nickel metal hydride battery cells and must be disposed of properly. Follow all applicable state and federal laws and regulations pertaining to proper battery disposal.

4.0 Change the rear ‘Sensing’ port bellows every 12 months unless there is evidence of damage to the bellows, in which case it should be changed immediately.

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Unscheduled Maintenance

The following procedures should be performed as required by suitably qualified personnel. Records should be kept of such maintenance following document retention polices.

WARNING:

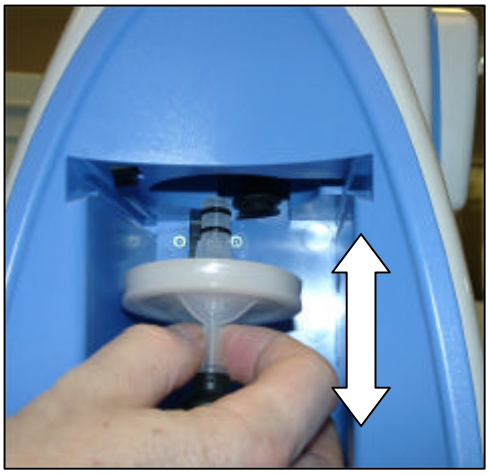
High voltages are present when the unit is operated from mains/AC or battery power. Disconnect the mains supply to the unit before removing the front cover. Disconnect the battery prior to any cable or electrical component removal, installation, or replacement.

Carefully observe the locations and routings of all cables and tubing removed while performing these procedures. These cables must be located exactly as they were before removal to ensure continued safe operation.

All screws must be tightened to 50 cNm torque.

Observe Electro-Static Discharge handling precautions wherever this sign is displayed:

1.0 SECONDARY FILTER REPLACEMENT



1.1 Ensure that there is no canister in the unit.
1.2 Press fully the canister latching button at the inside-rear of the blue canister holder to lower the bellows.
1.3 Pull down the filter and remove from the unit.
1.4 Insert a new filter up into the canister holder, taking care to locate it into the spigot. Push firmly upwards to ensure a positive engagement of the filter.

The filter should be changed in accordance with the Periodic Maintenance schedule. Identify the next due date of change on the filter.

2.0 'SENSING' PORT BELLOWS REPLACEMENT

2.1 Ensure that there is no canister in the unit.
2.2 Press fully the canister latching button at the inside-rear of the blue canister holder to lower the bellows.
2.3 Carefully remove the rear bellows from the sensing port spigot.
2.4 Carefully push the new bellows fully onto the rear spigot.

3.0 FRONT HOUSING REPLACEMENT

3.1 Remove the Front Housing, and replace with new assembly
3.2 Ensure that the protective film has been removed from the inside of the window of the new front housing prior to fitment.

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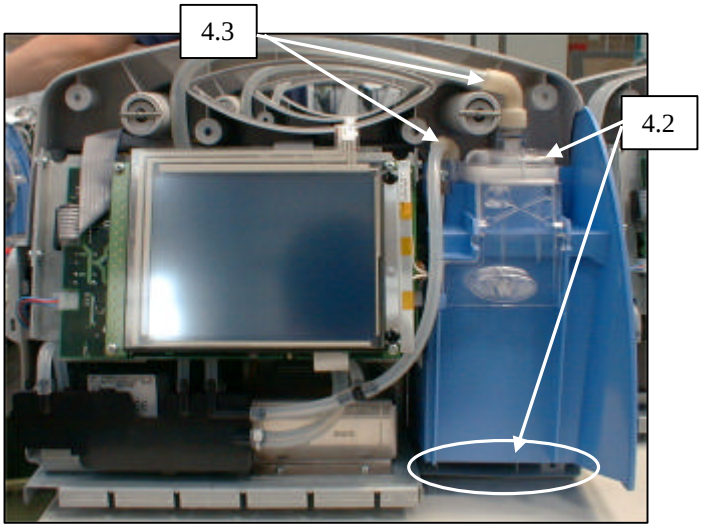
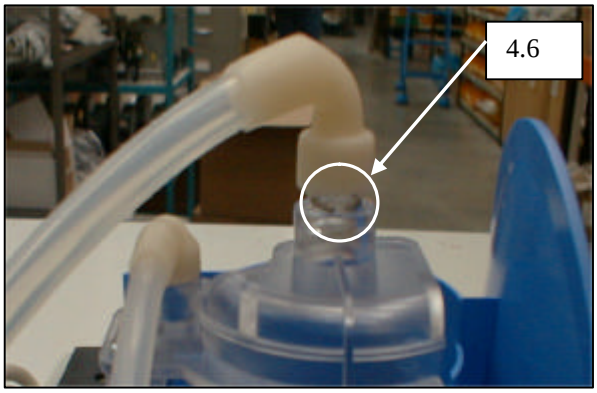
4.0 CANISTER HOUSING REPLACEMENT



4.1 Remove the Front Housing, and the Secondary Filter.
4.2 Disconnect the Battery.
4.3 Undo the 3 screws that secure the Canister Holder to the Rear Housing.
4.4 Disconnect the large and small tubes from the top of the Bellows Lever.
4.5 Disconnect the ribbon cable from the Canister Board.
4.6 Reverse the above procedure to install the new Canister Housing Assembly.

NOTE:
When re-connecting the Large and Small tubing, ensure that the elbow connectors are positioned as shown opposite.
The large elbow is designed to locate on a small notch at the front.



5.0 BATTERY REPLACEMENT

5.1 Remove the Front Housing.
5.2 Disconnect the tubing from the right side of the manifold.
5.3 Disconnect the battery from the charger board.
5.4 Unscrew the Battery Retaining Clip and withdraw the battery from the unit.
5.5 Remove the battery from the metal ‘clip’ and replace with a new pack.
5.6 Ensure that the leads exit the Battery Retaining clip as shown opposite.
5.7 Reverse the above procedure to install the new pack.

NOTE: The battery’s serial number and manufactured date is recorded on the side of the battery pack. Add the battery manufacturing date to the ‘Battery History’ label, and fix to the underside of the Therapy unit.

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6.0 DISPLAY/TOUCH PANEL REPLACEMENT

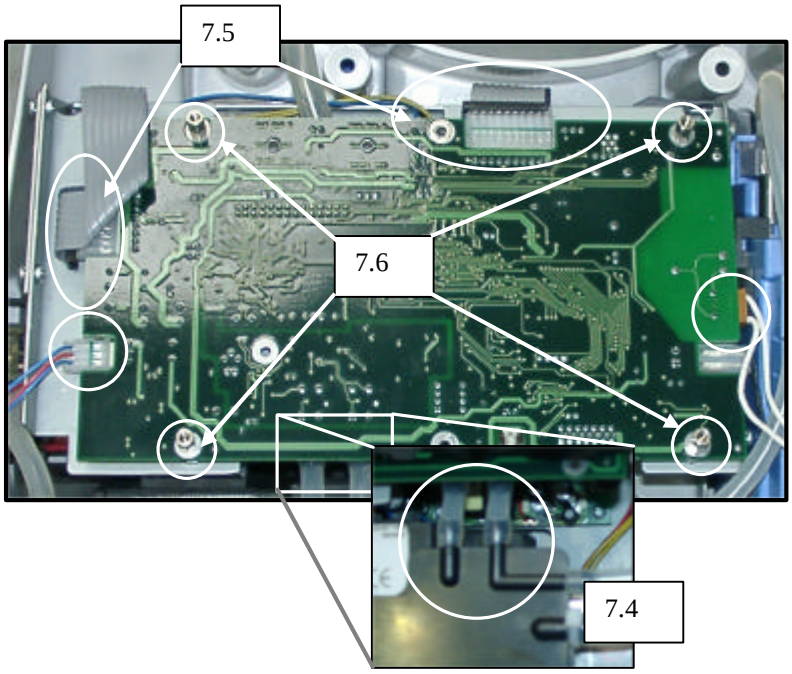
6.1 Remove the Front Housing.
6.2 Disconnect the battery.
6.3 Place the unit on its back on a flat surface.
6.4 Disconnect the Touch Panel ribbon cable from the top of the Control Board.
6.5 Disconnect the Display Ribbon Cable from the bottom of the Control Board. This is done by pulling the locking tab on the connector fully forward, and withdrawing the lead.

6.6 Disconnect the Inverter lead on the right side of the control board.
6.7 Remove the 4 screws holding the display to the control board.
6.8 Remove the display.
6.9 Fit new display by reversing the above. Lock the display connector by pressing the shroud fully into the connector.

NOTE: The Display Touch Screen may require calibration after a new unit has been fitted. Refer to the relevant Technical Bulletin for detailed instructions.

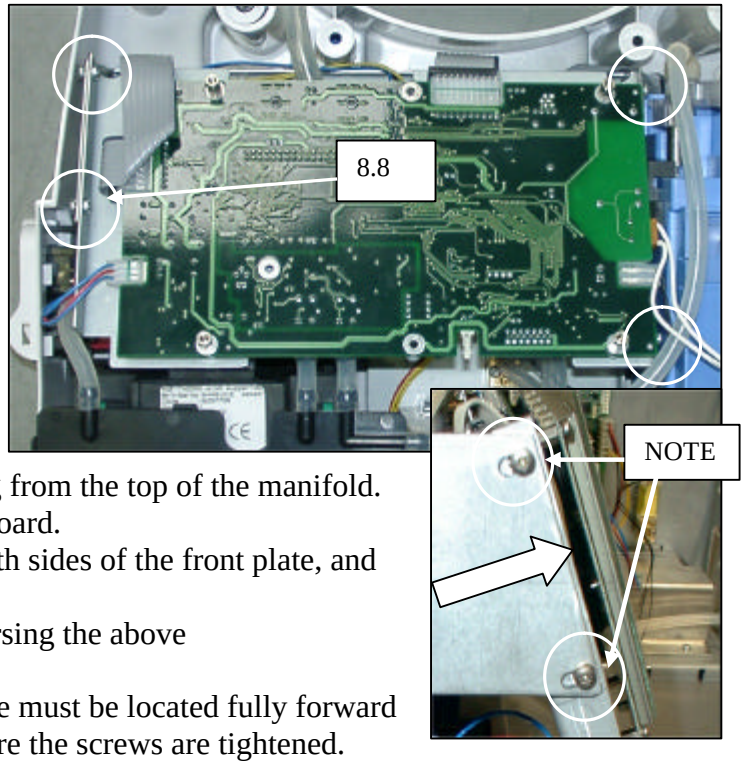
7.0 CONTROLLER BOARD REPLACEMENT

7.1 Remove the Front Housing.
7.2 Disconnect the battery.
7.3 Remove the Display/Touch Screen.
7.4 Disconnect the Tubing from the top of the Pump Manifold.
7.5 Disconnect the ribbon cables, Pump and Valve connectors from the Control Board.
7.6 Remove the 4 spacers, and remove the control Board.
7.7 Fit the new board by reversing the above.



NOTE: The Unit will require Configuration after the Controller Board has been replaced. Refer to the relevant Technical Bulletin for detailed instructions.

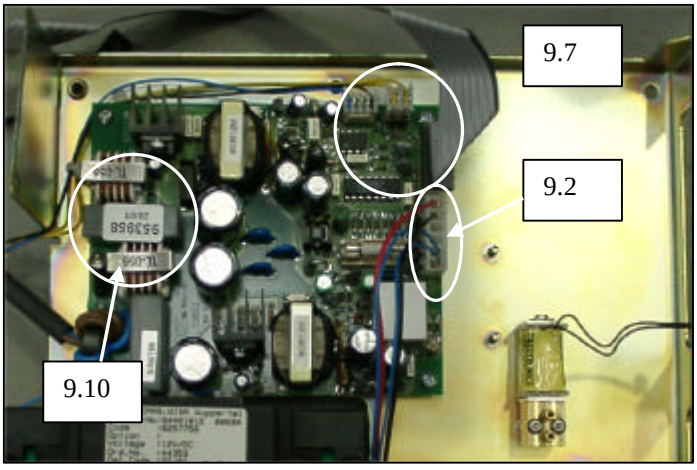
8.0 FRONT CHASSIS PLATE REPLACEMENT



8.1 Remove the Front Housing.
8.2 Disconnect the battery.
8.3 Remove the Canister Housing.
8.4 Remove the Display.
8.5 Disconnect both Ribbon Cables form the Controller Board.
8.6 Disconnect the Pump and Valve Connectors from the Control Board, and disconnect the tubing from the top of the manifold.
8.7 Remove the Controller Board.
8.8 Release the screws on both sides of the front plate, and remove from the unit.
8.9 Fit the new plate by reversing the above

NOTE: When re-fitting, the plate must be located fully forward in the slots on the rear plate before the screws are tightened.

9.0 CHARGER BOARD REPLACEMENT



9.1 Remove the Front Housing.
9.2 Disconnect the battery.
9.3 Remove the Canister Housing.
9.4 Disconnect all cables and tubing from the Controller Board.
9.5 Remove the Front Chassis plate, including the Display and Controller Board by removing the screws on both sides of the front plate.
9.6 Disconnect the Charger Board Live and Neutral wires from the IEC Mains Inlet Socket.
9.7 Disconnect the Ribbon Cable, the LED Wire and the On/Off switch wire from the Charger Board.
9.8 Remove the screws in each corner of the Charger Board.
9.9 Fit the new Charger by reversing the above.
9.10 The new boards batch number will be visible on the component side.

NOTE: The Charger Board that you fit may look different to the one shown here. However, the connection arrangements will be the same.

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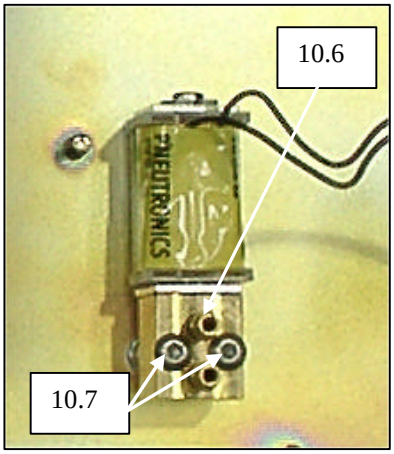
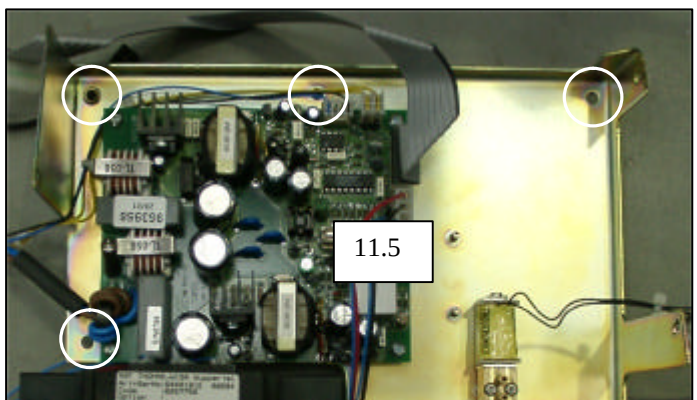
10.0 SOLENOID VALVE REPLACEMENT

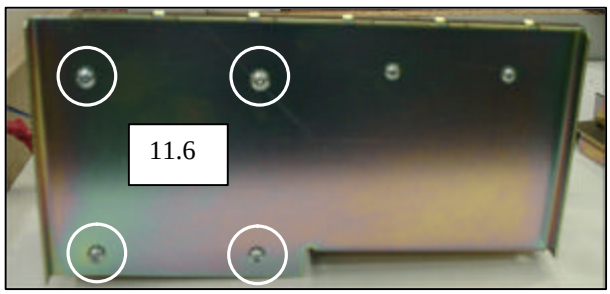
10.1 Remove the Front Housing.
10.2 Disconnect the battery.
10.3 Remove the Canister Housing.
10.4 Disconnect all cables and tubing from the Controller Board.
10.5 Remove the Front Chassis plate, including the Display and Controller Board by removing the screws on both sides of the front plate.
10.6 Disconnect the silicone tube from the top spigot of the Valve.
10.7 Using a 2mm Alan Key, undo the two screws securing the valve to the rear plate.
10.8 Fit the new Valve by reversing the above.

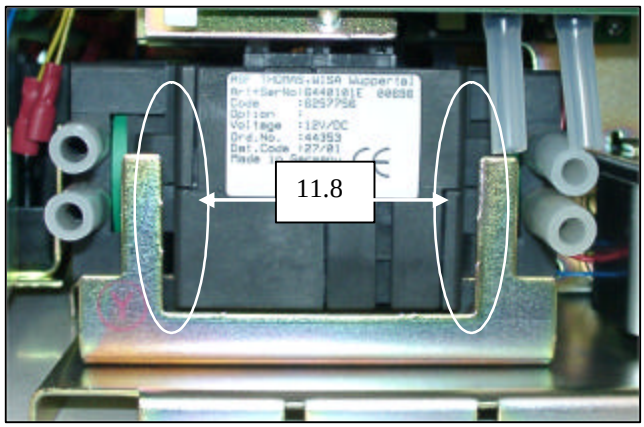


11.0 PUMP REPLACEMENT

11.1 Remove the Front Housing.
11.2 Disconnect the battery.
11.3 Remove the Canister Housing.
11.4 Remove the Front Plate with Display and Board.
11.5 Remove the six screws holding the Chassis Plate to the Rear Housing and withdraw the Chassis Plate.
11.6 Place the Chassis Plate on its back and unscrew the four screws holding the pump in place.
11.7 Remove the Manifold from the Pump, including the silicone tubing.
11.8 Fit the new pump in position. Ensure that the Pump Retaining Brackets are positioned with equal space between the bracket and the pump.
11.9 To re-assemble the unit, reverse the above procedure.







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12.0 REAR CHASSIS PLATE REPLACEMENT

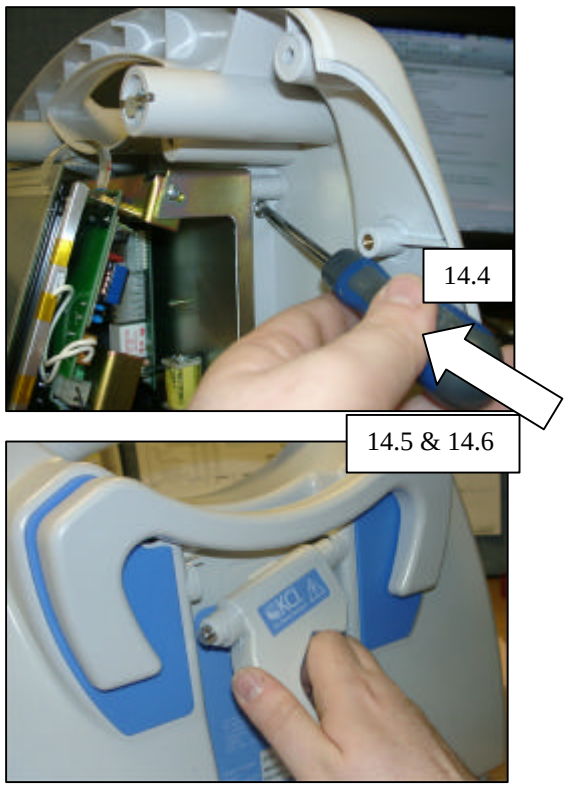
12.1 Remove the Front Housing.
12.2 Disconnect the Battery.
12.3 Remove the Canister Housing.
12.4 Remove the Front Plate with Display and Board
12.5 Remove the Charger and the Valve.
12.6 Remove the battery
12.7 Undo the six screws holding the plate to the Rear Housing, and withdraw the Chassis.
12.8 Remove the Pump.
12.9 Reverse the above procedure to reassemble the unit.

13.0 REAR HOUSING REPLACEMENT

13.1 Remove the Front Housing.
13.2 Disconnect the Battery.
13.3 Remove the Canister Housing.
13.4 Remove the 6 screws holding the complete chassis to the Rear Housing, and move the complete chassis to the right to access the IEC Inlet.
13.5 Disconnect the Charger Board from the IEC inlet.
13.6 Disconnect the LED lead from the Charger Board, and remove the Chassis from the rear housing.
13.7 Remove the Switch Protector and LED from the Rear Housing as described in section 20.
13.8 Remove the IEC switch as described in section 19.
13.9 Re-assemble the unit in the new Rear Housing by reversing the above procedure.

14.0 IV POLE CLAMP REPLACEMENT

14.1 Remove the Front Housing.
14.2 Disconnect the Battery.
14.3 Remove the Canister Housing.
14.4 Using a small screwdriver, press the IV Pole Clamp retaining pin to release the Clamp from the Rear Housing as shown.
14.5 Pull the Clamp down and away.
14.6 Insert the new Clamp into the recess on the exterior of the Rear Housing.
14.7 Push up and ensure that the clamp locks into position.
14.8 Re-assemble the unit by reversing the above procedure.



NOTE:
Ensure that the IV Pole Clamp is correctly secured and functions before re-assembling the

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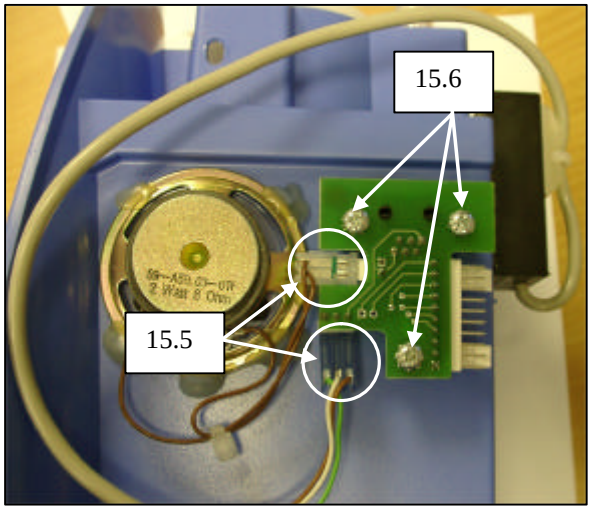
unit.

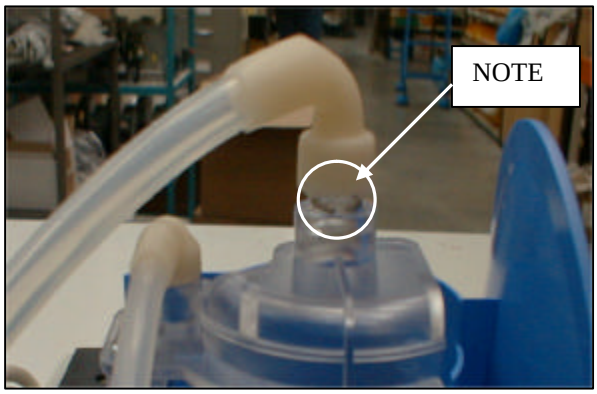
15.0 CANISTER BOARD REPLACEMENT

15.1 Remove the Front Housing.
15.2 Disconnect the Battery.
15.3 Remove the Canister Housing.
15.4 Locate the Board on the rear of the Canister Housing.
15.5 Disconnect the Sounder and the Level Sensor from the Board.
15.6 Remove the board from the Canister Housing.
15.7 Re-assemble the unit by reversing the above procedure



16.0 LARGE TUBING REPLACEMENT

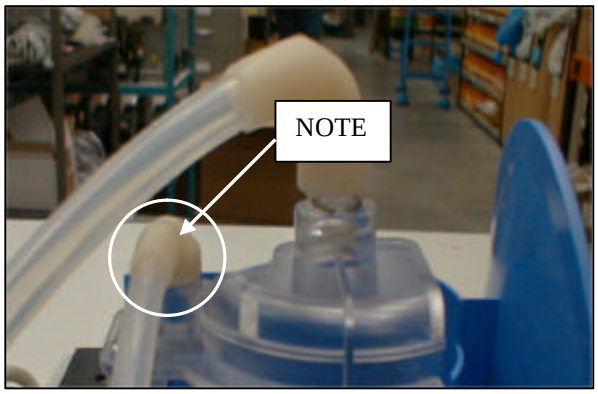
16.1 Remove the Front Housing.
16.2 Disconnect the Battery.
16.3 Disconnect the large tubing from the Manifold.
16.4 Disconnect the other end from the top of the Bellows Lever.
16.5 Re-fit the new tubing to the top of the Bellows Lever.
Re-assemble the unit by reversing the above procedure.



NOTE: The Tubing elbow is designed to fit in a notch on the front of the Bellows Lever, which ensures that the tubing is correctly dressed.

17.0 SMALL TUBING REPLACEMENT

17.1 Remove the Front Housing.
17.2 Disconnect the Battery.
17.3 Disconnect the large tubing from the top-right side of the Manifold.
17.4 Disconnect the tubing from the top spigot of the Valve.
17.5 Disconnect the tube from the top of the Bellows Lever.
17.6 Re-assemble the unit by reversing the above procedure.



NOTE: The Tubing elbow needs to be facing forward as shown opposite in order for the tubing to be routed correctly.

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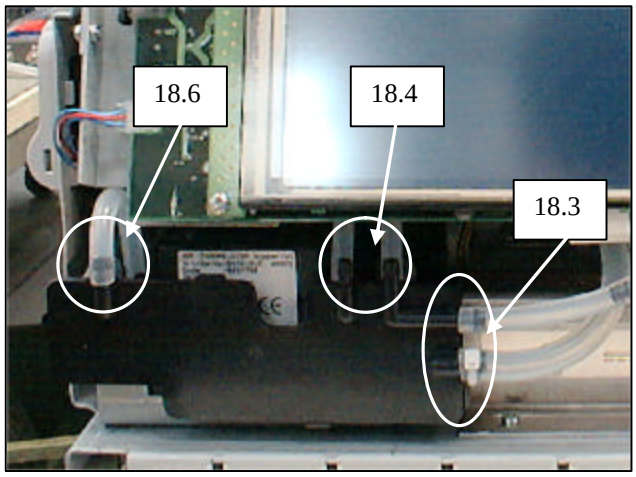
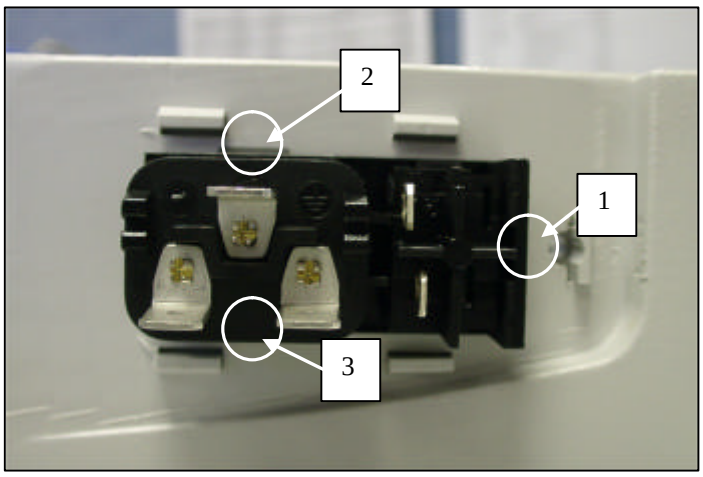
18.0 MANIFOLD REPLACEMENT

18.1 Remove the Front Housing.
18.2 Disconnect the Battery.
18.3 Disconnect the tubing from the right side, which goes to the Canister Holder.
18.4 Disconnect the tubing that connects the Manifold to the Controller Board.
18.5 Pull the manifold forward and off the pump tubing.
18.6 Remove the vent tube from the right side of the Manifold.
18.7 Re-assemble the unit by reversing the above procedure.



19.0 MAINS INLET/SWITCH REPLACEMENT

19.1 Remove the Front Housing.
19.2 Disconnect the Battery.
19.3 Remove the Canister Housing.
19.4 Unscrew the six screws holding the complete Chassis into the Rear Housing. Move the Chassis to the left to allow access to the switch.
19.5 Disconnect the Brown and Blue wires from the connector terminals.
19.6 Disconnect the switch wires.
19.7 One at a time, depress the IEC Inlet retaining tabs and gently push the switch out of the housing. Follow the sequence below.
19.8 Re-assemble the unit by reversing the above procedure



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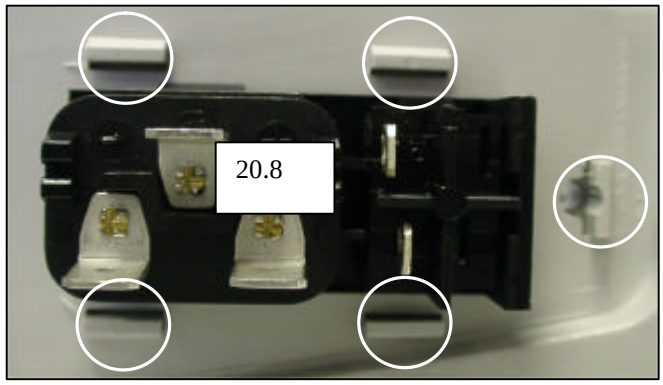
20.0 SWITCH PROTECTOR REPLACEMENT



20.1 Remove the Front Housing.
20.2 Disconnect the Battery.
20.3 Remove the Canister Housing.
20.4 Unscrew the six screws holding the complete Chassis into the Rear Housing. Move the Chassis to the left to allow access to the switch.
20.5 Disconnect the Brown and Blue wires from the connector terminals of the IEC Inlet.
20.6 Disconnect the wires from the switch, and disconnect the L.E.D wires from the Charger Board
20.7 Remove the IEC Inlet.
20.8 One at a time, depress the Switch Protector retaining tabs and gently push the part out of the housing.

NOTE: The Green L.E.D is glued into the Switch Protector. You will need to cut the L.E.D wires in order to remove the Switch Protector. A new L.E.D lead will need to be fitted to the new Switch Protector.

20.9 Fit the IEC lead and replacement Switch protector into the rear housing.
20.10 Apply a small amount of M4273654 adhesive to the side of the green L.E.D on the replacement L.E.D wire, and push fully into the L.E.D hole on the top of the Switch Protector.
20.11 Re-assemble the unit by reversing the above procedure from 20.6.

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Firmware Upgrade

WARNING! Starting this procedure will prevent the therapy unit from functioning until upgrade is successfully completed. Ensure that the correct Download software is installed on your PC and that you have the correct product software update to complete the process.

EQUIPMENT REQUIRED

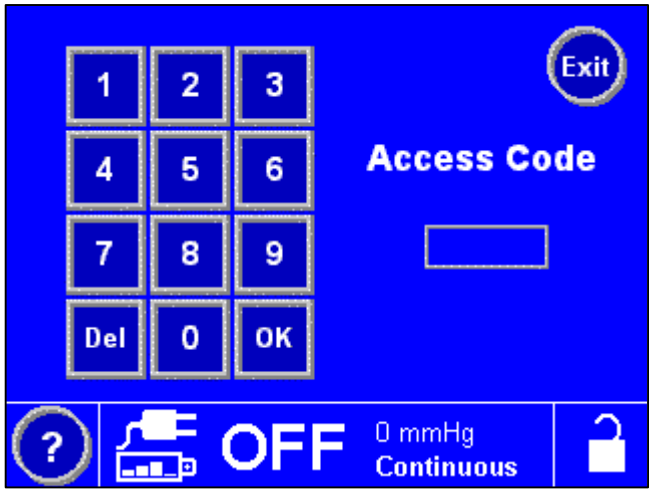
- PC with serial com port available, (preferably COM1), and either Windows 95, 98 or NT operating system.
- Serial upgrade cable, (MiniVAC type is acceptable) – M6243830
- PC Download software installed, available from UK Engineering
- V.A.C ATS Software upgrade file

SETTING UP

1. Install the PC Download software on the PC.
2. Connect the serial upgrade cable to a free serial port. If the port is not COM1, refer to the ReadMe.txt file for the correct command syntax to use other serial ports.

PROCEDURE

1. Switch on the therapy unit and press Utilities the Service. The following Access Code screen will appear.



2. Enter the software upgrade access code 524911 and press OK. The screen will go blank.

3.

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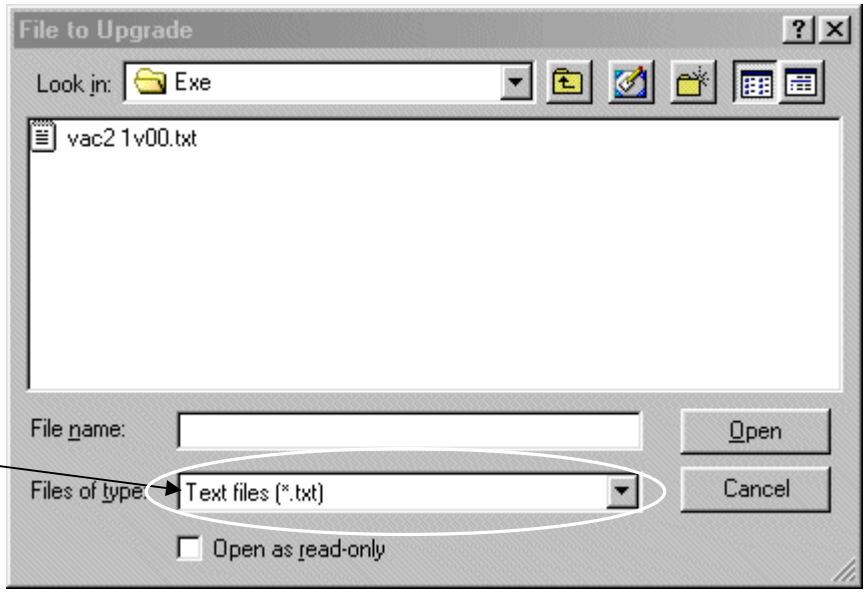
Switch off the therapy unit. Wait 3 seconds then switch on the Therapy Unit again. A short beep indicates that the therapy unit is ready to accept new software.

4. Connect the serial upgrade cable from the PC to the access port inside the canister holder.

5. On the PC, click Start ⇒ Programs ⇒ KCI ⇒ Download to start the download program. (If you have used a serial port other than COM1 you will need to use a shortcut with the correct command line syntax as defined in C:\Program Files\Download\ ReadMe.txt).



Select correct file type

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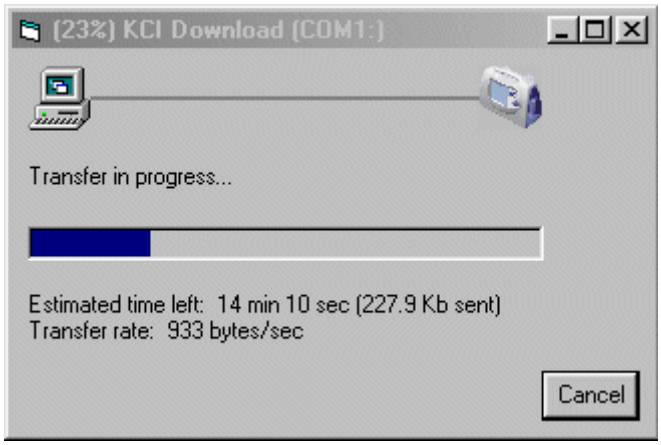
6. Select the file type which matches the software upgrade file extension. For example, if the file is VAC_ATS.txt then select type ".txt".

7. Using the file open dialogue as shown, find and open the correct software upgrade file.

8. The program will open communications with the therapy unit and begin transferring the new software. An estimate of the time required to complete the transfer is displayed.



9. When the transfer is complete, switch the therapy unit off and disconnect the serial cable. Switch the therapy unit on and press Utilities, then About. Check that the software version number is now correct.

NOTE:

For language upgrade, please refer to the instruction included with the language upgrade file.

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SPARES LIST

PART DESCRIPTION	KCI PART NO.
IV POLE CLAMP ASSEMBLY	6244807
IV POLE CLAMP - END CAP FRICTION PAD	3256013
MANIFOLD	3254220
CANISTER HOLDER ASSEMBLY	6251306
TUBE ASSEMBLY (SMALL BELLOWS)	6264476
TUBE ASSEMBLY (LARGE BELLOWS)	6264477
SOLENOID VALVE ASSEMBLY	6264526
WIRE ASSEMBLY- LED TO POWER SUPPLY BOARD	6265390
WIRE ASSEMBLY- INLET SWITCH TO POWER SUPPLY BOARD	6265391
TOUCHSCREEN WINDOW	3256204
REAR HOUSING ASSY - SPARES ONLY NUMBER	6268523
FRONT HOUSING ASSEMBLY	6268521
CANISTER PCB	6271139
BATTERY	4270547
CONTROLLER PCB	6271138
VACUUM PUMP	6257756
POWER SUPPLY / CHARGER BOARD	6271140
PUMP RETAINING BRACKET	3243308
REAR CHASSIS PLATE	3244713
10 WAY RIBBON CABLE	6243829
8 WAY RIBBON CABLE	6243828
SCREEN CHASSIS	3243307
SCREW - M3X16 BUTTON HEAD	7259183
SCREW - M4X8 PAN HEAD CW S/PROOF WASHER	7259185
SCREW - M3X6 PAN HEAD CW S/PROOF WASHER	7259184
BATTERY RETAINING BRK ASSEMBLY	6243115
SWITCH PROTECTOR	3258420
GREEN L.E.D WIRE ASSEMBLY	6265390
SWITCH / INLET	4268833
CANISTER LATCH	3266221
SCREW - M4X12 PAN HEAD CW S/PROOF WASHER	7259187
MAINS CORD (USA)	4268840
MAINS CORD (SHUKO)	4268742
MAINS CORD (UK)	4268743
SECONDARY FILTER	6248806
LARGE BELLOWS	4242002
POWER CORD RETAINING CLIP	3262615
MANUAL (ENGLISH)	6252203
SCREW - COUNTERSUNK M3 X 8MM	7259182
FILTER SPRING	3262613
SCREW M4 X 12MM	7259187
PIN - HANGER ARM - LARGE	3256524
DISPLAY AND TOUCH PANEL ASSEMBLY	6270514
ACTUATOR TONGUE	3266222
BATTERY FOAM SPACER	3249365
IV FRICTION PAD	3256009
BATTERY HISTORY LABEL	5964

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QA CHECKLIST

FOR THE LATEST REVISION OF THE QUALITY CONTROL CHECK LIST PN 3100059 PLEASE REFER TO YOUR LOCAL KCI DISTRIBUTOR

WOUND V.A.C® ATS QUALITY CONTROL CHECKLIST

PN M3100059

Serial #: **Barcode #:** **Location:**

Cleaned by: _____ **Date:** _____/_____ / ____

- ☐ 1 Power cord and plug are clean and undamaged

PUMP UNIT FUNCTIONS

- ☐ 2 The exterior of the pump unit is clean and undamaged.
- ☐ 3 All rubber pads are in place.
- ☐ 4 Hanger bracket and IV Pole Clamp are secure and operate correctly.
- ☐ 5 The power switch operates correctly.
- ☐ 6 Verify that canister latch will secure the canister.
- ☐ 7 Check function of leak alarm by operating therapy with open canister.
- ☐ 8 Set vacuum to 200mmHg and verify that pump reaches target with canister capped.
- ☐ 9 Hydrophobic filter changed (if required). If there is evidence that fluid has leaked past the filter, obtain an RMA and return the unit for repair. Do not open the unit.
- ☐ 10 Ensure that the two suction cups at the top of the canister chamber are clean and undamaged.
- ☐ 11 Check that Blockage alarm occurs when tubing is clamped
- ☐ 12 Release Valve Operation – Connect a manometer to the canister tube. Operate therapy at 125mmHg, turn therapy off. Ensure reading drops to <30mmHg in 10 seconds
- ☐ 13 Set therapy hours to zero
- ☐ 14 Check that the Canister Level Sensor operates correctly in the Engineering – Therapy screen. Do not open the unit.

OPERATOR DISPLAY

- ☐ 15 The Therapy On/Off function operates correctly.
- ☐ 16 All Options and their corresponding display screens and indicators operate correctly.
- ☐ 17 Status Bar function operates correctly on screen.
- ☐ 18 . Ensure that all labels required on this product are in their proper places and undamaged.
- ☐ 19 Ensure that the unit can be switched ON and OFF, on battery mode
- ☐ 20 Run the unit on battery mode for approximately 15 minutes.
- ☐ 21 Reconnect to AC power, ensure that on-screen indicator illuminates
- ☐ 22 Ensure that battery symbol displays during battery mode

DELIVERY QUALITY CONTROL CHECKLIST

Account Name ☐

- ☐ All Control Functions
- ☐ All Therapy functions

Technician Signature ☐

Date _____/ ____ / ____

QUALITY CONTROL VERFICATION CERTIFIED BY:

Technician Signature ☐

Date _____/____ / ____

PN M3100059 iss A

A COPY OF THIS COMPLETED CHECKLIST MUST BE PLACED IN THE UNIT HISTORICAL DATA FILE

SPECIFICATIONS*

CLASSIFICATION:

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide

Type B Equipment

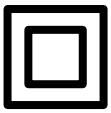
Class II Equipment with internal electrical power source.

PHYSICAL DATA	
Dimensions	14.6” (37cm)W x 11”(28cm)H x 7.1” (18cm)D
Weight	12.3lbs (5.6kg)
ELECTRICAL DATA	
Voltage	100 – 240 V ~
Frequency	50-60Hz
Maximum power consumption	70W
ENVIRONMENTAL DATA	
Storage Conditions	
Temperature range	-4°F (-20°C) to 140°F (60°C)
Relative humidity range	10% to 95% Non Condensing
Atmospheric pressure range	700hPa to 1060hPa
Operating Conditions	
Temperature range	+50°F (+10°C) to +86°F (+30°C)
Relative humidity range	30% to 75%
Atmospheric pressure range	500hPa to 1060hPa

*Specifications subject to change without notice.

ORDERING INFORMATION AND CONTACT ADDRESSES

HARDWARE



Class II Equipment

Type B Equipment

Alternating Current

ON

OFF – part of the equipment **only**

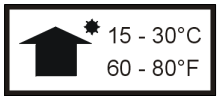
STERILE DISPOSABLES

LOT / BATCH

METHOD OF STERILIZATION - IRRADIATION

EXPIRATION DATE

DATE OF MANUFACTURE



STORAGE CONDITIONS

REFER TO USERS INSTRUCTIONS

FRAGILE

KEEP DRY

SINGLE USE ONLY

The V.A.C.® ATS system CONFORMS WITH THE MEDICAL DEVICES DIRECTIVE(93/42/EEC)

EEC DIRECTIVE

The **KCI V.A.C.â ATS system** is in conformity with the Medical Device Directive (93/42/EEC) and has been subject to the conformity assurance procedures laid down in the Council Directive.

KCI Medical Ltd. Engineering Division is certified by AMTAC Certification Services Ltd. as an approved medical device manufacturer.

The **KCI V.A.C.â ATS system** conforms to the following International standards:
EN 60601-1-1:1990 including A13:1996, CAN/CSA-C22.2 No 601.1-M90, UL2601-1:1994 1st Edition-Amended 1996, EN60601-1-2:1993.

Ordering Information:

V.A.C.® ATS 110v Therapy unit	M8259968
V.A.C. ® ATS 230v Therapy unit	M8259967
T.R.A.C.™ System Small Black Foam Dressing (10/Carton)	M6275051
T.R.A.C.™ System Medium Black Foam Dressing (10/Carton)	M6275052
T.R.A.C.™ System Large Black Foam Dressing (10/Carton)	M6275053
V.A.C. ® ATS T.R.A.C.™ System Canister with Gel (10/Carton)	M6275063

Please contact your KCI representative for a full product catalogue.

Contact Addresses:
For location and contact information of KCI operations world wide, visit the KCI website at www.woundvac.com**.** For additional sales and technical information concerning the V.A.C. ATS, please contact your local KCI representative or:

USA Representative:
KCI USA, Inc.
8023 Vantage Dr.
San Antonio, TX 78230
USA
Phone: 1-888-275-4524 or 1-877-woundvac
Fax: 1-800-275-3417
www.woundvac.com

CANADA Representative:
KCI Medical Canada Inc
7170 Edwards Blvd
Mississauga, Ontario L5S 1ZL
Canada
Phone: 1-905-565-7187
Fax: 1-905-565-7270

Outside USA & Canada:
KCI International, Inc.
8023 Vantage Dr.
San Antonio, TX 78230
USA
Phone: 1-210-255-6460
Fax: 1-210-255-6991
www.woundvac.com

Manufactured For
Corporate Headquarters:
KCI USA, Inc.
8023 Vantage Dr.
San Antonio, TX 78230 USA
1-877-WOUNDVAC

EU Representative:
KCI Medical Ltd
11 Nimrod Way
Wimborne, Dorset
BH21 7SH
ENGLAND

In case of emergency, contact local emergency number or treating physician.

All trademarks and service marks designated herein are proprietary to KCI, its affiliates and licensors.
Trademarks designated "®"are registered in at least one country where this product is commercialized, but not necessarily in all such countries.
The V.A.C.® (Vacuum Assisted ClosurE ®) system and certain components are subject to one or more of the following patents:
USA -- 4,969,880 5,100,396 5,261,893 5,527,293 5,636,643 5,645,081 6,071,267 6,135,116 6,142,982
6,398,767, 6,345,623, D344,735, D364,679, D406,899, D469,176, D469,175;
EC -- EP0777504 EP0688189 EP0620720 EP0865304 EP0465601 EP1088569 DM/032185; other patents pending.
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